



900001-2115

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Deaton et al.
Serial No.: 10/625,359
Filing Date: 07/23/2003
Docket Number: 900001-2115
Title: Apparatus For Electronic Dosage Counter

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AUTHORIZATION TO CHARGE REQUISITE FEES

Sir:

In response to the Office Action mailed December 13, 2005 in connection with the above-referenced patent application, Applicant hereby authorizes the Commissioner to charge the One (1) Month Extension of Time Fee for \$120.00 pursuant to 37 CFR §1.17, for a fee total \$120.00, to our Deposit Account No. 50-2543.

Furthermore, the Commissioner is hereby authorized to charge any additional fees as necessary or credit any overpayment to our Deposit Account Number 50-2543.

If there are any questions, please call the undersigned at the telephone number indicated below.

Respectfully submitted,

KOS PHARMACEUTICALS, INC.

Karen P. Bechtold
Karen P. Bechtold, Esq.
Registration No. 52,166
Attorney for Applicant

Kos Pharmaceuticals, Inc.
1 Cedar Brook Drive
Cranbury, NJ 08512
Tel.: 609.495.0524
Fax: 609.495.0907

Date: April 6, 2006

CERTIFICATION UNDER 37 C.F.R., §1.10

I hereby certify that the attached papers are being deposited with the United States Postal service as: Express Mail Post Office to Addressee" Service under 37 C.F.R. §1.10 on 04/06/06 and is addressed to Commissioner for Patents, Mail Stop AMENDMENT, P.O. Box 1450, Alexandria, VA 22313-1450.

ED055674231US

Express mail no.

Oscar Espinosa



PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Daniel Deaton, Thomas W. Ruckdeschel,
Perry Genova, and Warren Jewett

Serial No.: 10/625,359

Filing Date: 07/23/2003

Title: APPARATUS FOR ELECTRONIC DOSAGE COUNTER

Docket Number: 900001-2115

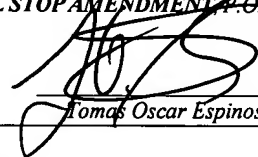
MAIL STOP AMENDMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

CERTIFICATION UNDER 37 C.F.R. 1.10

I hereby certify that the attached papers are being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Service under 37 C.F.R. 1.10 on April 6, 2006 and is addressed to: MAIL STOP AMENDMENT P.O. Box 1450, Commissioner for Patents, Alexandria, VA 22313-1450.

EL 055674231 US
"Express Mail Label No."


Tomas Oscar Espinosa

TRANSMITTAL LETTER

Dear Sir:

Enclosed herewith for filing in the United States Patent and Trademark Office for the above-referenced application are the following documents:

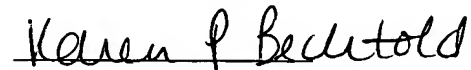
1. Response to Office Action
2. Copy of Office Action mailed December 13, 2005
3. Return Postcard
4. Request for One Month Extension of Time
5. Authorization to Charge Deposit Account

Please charge our deposit account, 50-2543, the required one (1) month extension of time fee of \$120.00 pursuant to 37 C.F.R. §1.17 for a total charge to our deposit account of \$120.00. For this purpose we enclose a duplicate copy of this document.

If there are any questions, please call the undersigned at the telephone number indicated below.

Respectfully submitted,

KOS PHARMACEUTICALS, INC.



Karen P. Bechtold, Esq.

Registration No. 52,166

Attorney for Applicant

Kos Pharmaceuticals, Inc.
1 Cedar Brook Drive
Cranbury, NJ 08512-3618
Tel: 609.495.0500
Fax: 609.495.0907

Date: April 6, 2006



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,359	07/23/2003	Daniel M. Deaton	900001-2115	8226

7590

12/13/2005

Kos Life Sciences, Inc.
1001 Brickell Bay Drive
Miami, FL 33131



EXAMINER

BUNIN, ANDREW M

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 12/13/2005

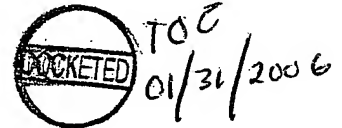
Please find below and/or attached an Office communication concerning this application or proceeding.

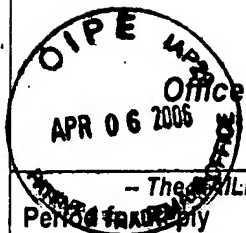
RECEIVED
KOS PHARMACEUTICALS, INC.
LEGAL DEPT.

BY: VPB

DATE: 1/31/06

**Docket
&
File**





Office Action Summary

Application No.

10/625,359

Applicant(s)

DI JON ET AL.

Examiner

Andrew M. Bunin

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor (US 6029659). O'Connor discloses an apparatus for dispensing medication comprising at least one canister 11 containing the medication to be dispensed, the canister 11 being movable in a first and a second direction. O'Connor continues to disclose a mouthpiece 12 providing a point of dispensation for the medication from the canister 11 to a user when the canister is moved in a first direction. In addition, O'Connor discloses a switch means 50 for completing an electrical circuit when the canister 11 moves in a first direction and opening the electrical circuit when the canister 11 moves in a second direction, wherein the switch means 50 is oriented to enable operational connectivity with the canister or canister discharge (see Figure 7). O'Connor includes a counter module 40 for performing a count upon the closure of the electrical circuit and displaying a dispensation history (41) of the medication in the canister 11. O'Connor discloses a seal 718 isolating the counter module 40 from the mouthpiece and the canister to prevent contamination as shown in Figure 7.

As for claims 2-4 and 6, O'Connor discloses the dispensation history that includes the number of doses of medication remaining in the canister (column 3, lines 58-61). In

Art Unit: 3743

addition, O'Connor teaches the history including the number of doses taken of a dosage sequence the number of doses taken over a period of time (column 5, lines 19-24 and column 4, lines 52-55). O'Connor continues to disclose the dispensation history including time since the last dispensation of the medication (column 5, lines 46-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor. It would have been obvious to a person having ordinary skill in the art at the time of the invention to allow this device to be capable of varying the period of time for a dosage in order for the device to be reused with different medicines of varying dosage requirements.

Claims 7, 9, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor. O'Connor has disclosed the display portion 41 of the counter module 40 is on the back of the mouthpiece as shown in Figure 6. However, placing the display portion on the front of the mouthpiece or on the side of the mouthpiece are both equivalents of placing the display portion on the back of the mouthpiece. Accordingly, the examiner considers the selection of such to be mere

Art Unit: 3743

obvious matter of design choice and as such does not patentably distinguish these claims over the prior art.

Claims 10, 11, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Rand et al. (US 6431168). O'Connor has taught everything except the switch means including an electrically conductive contact imbedded in the seal. However, Rand et al. teach a similar apparatus for dispensing medication that includes a switch means 44 with an electrically conductive contact 46/47 imbedded in the seal 40. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of O'Connor to replace this switch means with the switch means taught by Rand et al. in order to increase the reaction speed of the switch from movement of the canister as well as improve the accuracy of having a switch react via conductive contact versus force of contact.

As for claims 11 and 12, O'Connor discloses a portion of the counter module 40 disposed external to the mouthpiece 12 as shown in Figure 5. It is considered a mechanical equivalent to place a portion of the counter module within the mouthpiece. In addition, Rand et al. device teaches the counter module as being partially disposed within the mouthpiece especially if the mouthpiece includes portion 3 until 20. Accordingly, the examiner considers the selection of such to be mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Rand et al. O'Connor discloses everything except the seal including

Art Unit: 3743

a ramp that acts upon the switch. However, Rand et al. teaches the seal 40 passing above switch 44 including a ramp 47/46 that act upon the switch means 44 when the canister 2 is moved in the first direction as shown in Figures 8 and 9. In addition, Rand et al. teaches the switch means 44 as being mounted on a circuit board 49 (column 8, lines 17-22) and is acted upon by a ferrule portion 11 of the canister 2, the switch means 44 being isolated from the canister by a second seal 5 (column 4, lines 12-20). Rand et al. also teaches the seal 40 being made of conductive material (sections 47/46). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify O'Connor with the switch means system of Rand et al. in order to improve the reaction time of the circuit.

Claims 16-19 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Jewett et al. (US 5544647). O'Connor discloses everything except the switch means as being a water resistant dome switch. However, Jewett et al. teach a similar device to O'Connor including a switch means 42 that is a water resistant dome switch (column 7, lines 45-55). Jewett et al. continues to disclose the dome switch 42 as being mounted substantially parallel to an axis of travel of the canister 16 and is capable of being acted upon by a ferrule of the canister (Figure 3). Jewett et al. also teaches the dome switch 42 as being mounted on a platform (two lines connected to 46 in Figure 4) that extends perpendicular to the axis of travel of the canister 16 into the mouthpiece 22 and is acted upon by an end portion of the canister as shown in Figures 1 and 3. As for claim 19, although Jewett et al. don't explicitly teach the dome switch as being mounted on a top surface of an actuator sump, this

Art Unit: 3743

would be equivalent to placing the dome switch on a platform as stated above.

Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Jewett et al. and further in view of Rand et al. O'Connor and Jewett et al. teach everything except the switch means as being comprised of two open contacts that are in electrical communication with the counter module. However, Rand et al. disclose the switch means comprising two open contacts (46 and 47) that are in electrical communication with the counter module and a conductive surface of the canister 2 to close the contacts 46/47 when the canister moves in the first direction (column 8, lines 8-33). Rand et al. continues to teach the two open contacts 46/47 are located on a top surface of an actuator sump and are acted upon by a metallic end portion of the canister 2 as shown in Figures 8 and 9. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device taught in the prior art to use a direct electrical connection between the counter module and a canister in order to increase the accuracy and speed of reaction for each dosage.

As for claims 22 and 23, Jewett et al. continue to disclose the dome switch 42 as being acted upon by the actuator as the canister 16 moves in the first direction shown in Figure 3. Placing the dome switch on an actuator sump or on an exterior surface of the mouthpiece are both considered mechanical equivalents to placing the dome switch on

Art Unit: 3743

a platform. Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

As for claims 24-31, Jewett et al. discloses the switch means as being formed of a movement sensor (column 9, lines 1-7). In addition, Jewett et al. teaches the movement sensor as being a light sensor, the light sensor emitting light and receiving a reflected signal, upon movement of the canister the reflected signal is altered and the altered signal is detected by the sensor providing input to the circuitry and changes the count (column 7, lines 63-67). The sensor is located to act upon and detect a changing position of the canister as it is moved in the first direction (column 8, lines 12-16). Jewett et al. also teaches the movement sensor as being an acoustic sensor, the acoustic sensor emitting an acoustic signal and receiving a reflected signal, upon movement of the canister the reflected signal is altered, and the altered signal is detected by the sensor closing contacts housed therein (column 6, lines 42-51). The acoustic sensor taught by Jewett et al. is capable of sensing the acoustic signature of the aerosolization of a metered dose dispensation (column 6, lines 42-44). Lastly, Jewett et al. teaches the movement sensor as being a magnet sensor, upon movement of the canister the magnetic signature of the canister is altered which is detected by the sensor providing input to the circuitry and changes the count (column 8, lines 53-67). As stated above, the sensor is "triggered" upon detection of a changing geometry of the canister as it is moved in the first direction (column 8, lines 12-16). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention

Art Unit: 3743

to modify O'Connor to include the sensor and dome switch taught by Jewett et al. in order to quickly and efficiently keep track of the dosage for a user.

Claims 24, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Mishelevich et al. (US 5363842). O'Connor discloses everything except the switch means as being formed of a movement sensor.

Mishelevich et al. teach a switch means with a motion sensor 222 that is a pressure sensor 240/230 and located in an actuator sump for detecting a change in pressure upon the dispensation of the medication from the canister. The pressure sensor taught by Mishelevich et al. is considered a mechanical equivalent of the other movement sensors taught by Jewett et al. for improving the technology of a counter device.

Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor in view of Rand et al. O'Connor has taught everything except a ramp seal isolating the switch means from the canister. However, Rand et al. teaches a ramp seal 46/47 connected to body 40 isolating the switch means 44 from the canister 2 to prevent contamination, wherein the ramp seal 46/47 is acted upon by the canister upon movement of the canister in the first direction and wherein the ramp seal 46/47 acts on the switch means to close the electrical circuit as shown in Figures 8 and 9. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the

Art Unit: 3743

invention to modify O'Connor with the switch means system of Rand et al. in order to improve the reaction time of the circuit.

Claims 35-37, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor.

As for claims 35-37 and 39, O'Connor discloses the dispensation history that includes the number of doses of medication remaining in the canister (column 3, lines 58-61). In addition, O'Connor teaches the history including the number of doses taken of a dosage sequence the number of doses taken over a period of time (column 5, lines 19-24 and column 4, lines 52-55). O'Connor continues to disclose the dispensation history including time since the last dispensation of the medication (column 5, lines 46-55).

Claims 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor. O'Connor discloses a ferrule portion of the canister 11 acting upon a ramp seal 51. O'Connor continues to teach the counter 40 and ramp seal 51 as being formed in a common component. In addition, O'Connor discloses a sump for a nozzle of the canister wherein the counter, ramp seal and sump are formed as a common component as shown in Figure 5. The device's common component of O'Connor is capable of being injection moldable. In addition, this device's common component is capable of being adaptable to canister holders for a variety of canister shapes and sizes. O'Connor's common component is adaptable to canister holders for a variety of canister shapes and sizes. In addition, it is considered well known in the art that this device is adaptable to canister holders for a variety of canister shapes and sizes for

Art Unit: 3743

many different users. This device also includes the components including a canister holder, a canister, a mouthpiece, and a counter, wherein the counter is adaptable for use with a canister holder, canister, and a mouthpiece capable of being made of a variety of sizes and shapes. Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 6446627, US 6138669, and US 5505192

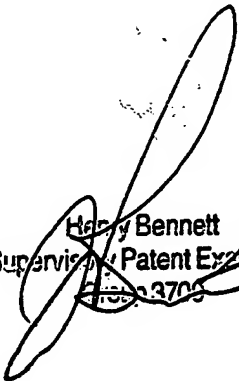
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AMB
12/07/05


Harry Bennett
Supervisory Patent Examiner
Art Unit 3743

103/00 RANDOLPH

Organization
U.S. DEPARTMENT OF COMMERCE
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
IF UNDELIVERABLE RETURN IN TEN DAYS
OFFICIAL BUSINESS

AN EQUAL OPPORTUNITY EMPLOYER

U.S. OFFICIAL MAIL
FIRST CLASS
PERMIT NO. 1000
ALEXANDRIA, VA
02 1A
0004204478 DEC 13 2005
MAILED FROM ZIP CODE 22314

331310204 1BC4 17 12/20/05
FORWARD TIME EXE RTH TO SEND
KOS PHARMACEUTICALS
2200 N COMMERCE PKWY STE 300
WESTON FL 33326-3258
RETURN TO SENDER

RECEIVED
DEC 28 2005
USPTO MAIL CENTER

PTENT & TRADEMARK OFFICE
APR 06 2006
O I P E

BEST AVAILABLE COPY